

PCT

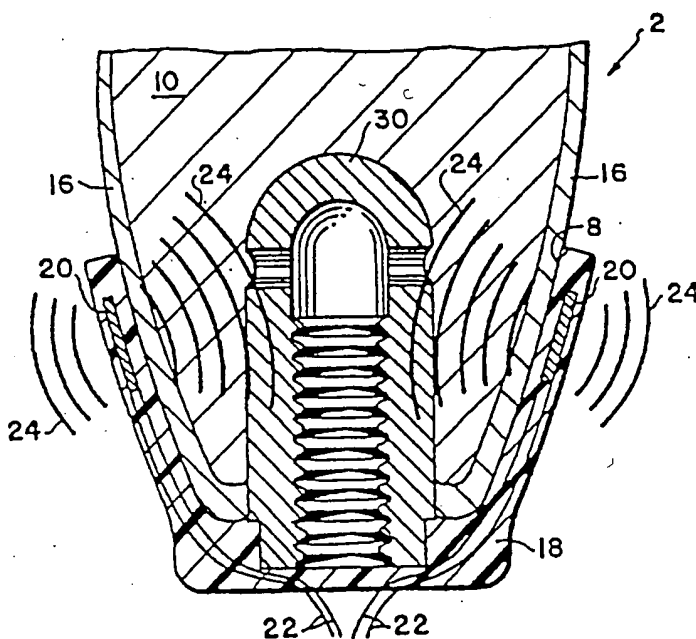
WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61B 17/56, A61C 19/06	A1	(11) International Publication Number: WO 95/33416 (43) International Publication Date: 14 December 1995 (14.12.95)
(21) International Application Number: PCT/US94/11233 (22) International Filing Date: 5 October 1994 (05.10.94) (30) Priority Data: 08/257,773 9 June 1994 (09.06.94) US (71) Applicant: SONEX INTERNATIONAL CORPORATION [US/US]; P.O. Box 533, Brewster, NY 10509 (US). (71)(72) Applicants and Inventors: <u>BOCK</u> , Robert, T. [US/US]; RD6 Drovers Lane, Brewster, NY 10509 (US). DE LUCA, John, P. [US/US]; 3340 Runnymede Place, N.W., Washington, DC 20015 (US). (74) Agent: DE LUCA, John, P.; Watson, Cole, Grindle & Watson, Suite 1000, 1400 K Street, N.W., Washington, DC 20005 (US).	(81) Designated States: BR, CA, JP, KR, NO, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.	

(54) Title: ULTRASONIC BONE HEALING DEVICE FOR DENTAL APPLICATIONS



(57) Abstract

Non-invasive apparatus for accelerating the process of jawbone healing and regeneration, reattachment of traumatically loosened teeth (12) to the jawbone, or osseointegration of implants (30) in a patient, including at least one piezoelectric transducer (20) and connections (11, 22) to transmit ultrasonic frequency electrical current to the piezoelectric transducer. The ultrasonic frequency electrical current transmitted to the piezoelectric transducer causes the transducer to contract and expand volumetrically in response to a changing electrical field to generate pressure wave vibrations of ultrasonic frequency that are coupled to the bone (10).

BEST AVAILABLE COPY

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TC	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

## ULTRASONIC BONE HEALING DEVICE FOR DENTAL APPLICATIONS

BACKGROUND OF THE INVENTION

This invention relates to bone healing devices. More particularly, the invention is concerned with an apparatus for facilitating the use of ultrasonic energy to significantly accelerate repair, grafting and healing of bone of patients impacted by periodontitis and other dental diseases effecting the oral cavity. The invention is particularly effective to improve the success and speed of osseointegration of dental implants and reattachment of traumatically loosened teeth.

A later stage of the periodontal disease in adults is the deterioration and loss of bone supporting the teeth. Numerous attempts have been made to reverse the deterioration and to heal the bone in the oral cavity by electrical means. The application of high frequency electrical currents by electrodes piercing the soft tissue and connecting to the bone has been demonstrated to accelerate healing, but it has also increased the possibility of infection in the invaded tissue. Due to the complications of infections, these procedures are no longer in use, and in general, the medical community relies on the natural, however long, healing process.

During currently employed directed tissue regeneration procedures, the surgeon typically

separates the gums from the deteriorated section of the jawbone, forming a pocket adjacent the surface of the bone that is filled with a two component system comprising freeze dried crushed bone and medication. The medication is sealed by a membrane implant and the membrane is sealed in place by reattachment of the gums around the membrane.

The final stage of periodontal disease is exemplified by extensive deterioration of bone resulting in the loss of teeth. Teeth can be replaced by implants, which involves a surgical procedure consisting of the installation of metal posts into the jawbone; the osseointegration of the posts and the bone; and the installation of artificial teeth onto the implanted posts utilizing anchoring screws. The implanted posts typically are coated with either plasma-sprayed titanium, hydroxyapatite, or other similar materials. Finely ground filler materials are used to reinforce porous bone and implant interface and to improve osseointegration of implants. The materials include freeze dried bone, natural coral and synthetic materials. While the addition of these materials generally improve the strength of porous and inadequate bone, the speed of healing and a complete osseointegration is still controlled by the natural healing process, which at times takes as long as six

months. The probability of movement of the implants during the healing time, resulting in a less than adequate bond, is proportional with the elapsed time required for osseointegration.

5           A further problem associated with the repair, grafting and healing of bone is that bacterial contamination, which despite all efforts, eventually occurs at the site, can impede the process of healing. Accordingly, it is desired to reduce or impede  
10       bacterial contamination to thereby improve and accelerate healing.

          What has occurred to date is that notwithstanding the teachings of the prior art, the ability to speed up healing effectively, inexpensively, and easily in a  
15       home environment has remained unsolved.

#### SUMMARY OF THE INVENTION

          Responding to the above-described unresolved needs, the invention provides a non-invasive method, by  
20       periodic (e.g., daily) application of ultrasound in the oral cavity, to speed up healing of bone and osseointegration of implants and to speed up the reattachment of teeth to the jawbone after traumatic loosening of teeth. The invention employs a  
25       piezoelectric device.

In one embodiment, the invention utilizes at least one piezoelectric transducer positioned in the oral cavity, driven by ultrasonic frequency current from a power supply located outside of the oral cavity, and  
5 radiating high frequency low intensity ultrasonic energy from the transducer through the gingival tissues or the teeth or both into the jawbone.

According to a feature of the invention, a relatively inexpensive disposable ultrasonic transducer  
10 may be fitted to the anatomy of a patient. The transducer may be used with a reusable ultrasonic power supply that could be utilized by multiple patients in a hospital setting. The external power supply may also be reused by transferring to another patient after that  
15 the full course of treatment has been completed by one in a home environment.

Another feature of the invention is a method for controlled and accurate positionment of the transducer at the optimum location for the treatment. The  
20 accuracy of such positionment is independent of the skill and the dexterity of the patient.

Yet another feature of the invention is to facilitate the absorption of the medication into the soft and hard tissues of the oral cavity. Further  
25 aspects, features and advantages of the invention will

be apparent from the examination of the specification, drawings and claims.

Another feature of the invention is to reduce bacterial contamination by retarding bacterial growth and propagation at the site.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, certain exemplary modes of carrying out the present invention are shown for illustrative purposes:

Fig. 1A is a perspective view of an ultrasonic bone healing device according to the invention shown in position adjacent the teeth of a patient;

Fig. 1B is a cross-sectional view of the invention taken along line 1B-1B of Fig. 1A as used during the directed tissue regeneration procedure;

Fig. 2A is a perspective view of another embodiment of the invention for use in osseointegration of implants;

Fig. 2B is a cross-sectional view of the invention taken along line 2B-2B of Fig. 2A as used during osseointegration of implants;

Fig. 3A is a perspective view of an embodiment of the invention employing an ultrasound transmitting gel interface to the skin sealed from the outside environment.

Fig. 3B is a cross-sectional view of the invention taken along line 3B-3B of Fig. 3A as used during osseointegration of implants;

5 Fig. 4A is a perspective view of an embodiment of the invention for facilitating osseointegration where the transducer is directly attached to the implant;

Fig. 4B is a cross-sectional view of the invention taken along line 4B-4B of Fig. 4A as used during osseointegration of implants;

10 Figs. 5A and 5B show an embodiment similar to Figs. 4A and 4B which employs a multilayer stacked piezoelectric transducer device;

15 Fig. 6A is a perspective view of an embodiment of the invention for facilitating osseointegration where the transducer is constructed as a multilayer stacked piezoelectric device that is held in position during the treatment by the teeth of the opposing jaw;

20 Fig. 6B is a cross-sectional view taken along line 6B-6B of Fig. 6A as used during osseointegration of implants;

25 Figs. 7A, 7B and 7C show an arrangement similar to Figs. 6A and 6B employing an elongated transducer device where the ultrasonic energy is transmitted through one or more teeth to the jawbone and the bone healing device is held in place by the teeth of the



opposing jaw for use in a directed tissue regeneration procedure;

Figs. 8A, 8B and 8C show an embodiment of the invention similar Figs. 6A and 6B employing a multilayer transducer; and

Fig. 9 shows an osseointegration application where the transducer produces ultrasonic energy for transmission to the jawbone through the implant..

#### 10 DESCRIPTION OF THE INVENTION

Referring in detail to the drawings, the reference numerals herein refer to the like numbered elements in the drawings. In the following discussion, unless otherwise qualified, the term "ultrasound" refers to either continuous wave ultrasound or a repetitive burst type ultrasonic modality.

According to one theory, when ultrasonic frequency pressure waves are applied to the bone, the bone creates microcurrents within its structure which enhances the healing process. By bombarding the jawbone with ultrasonic pressure waves through the soft tissue or the teeth, electric current is generated internally within the bone without breaking the skin, providing a non-invasive modality.

According to another theory, osteoblast cell membrane capacitance and the kinetics of the ion

binding pathway may be modified by ionic displacement due to the local interfacial pressure waves delivered by the ultrasonic bombardment of the tissue. This ionic displacement may be the physical trigger for a biochemical cascade as predicted by the electrochemical information transfer hypothesis. Other mechanisms may also be causative or contributing factors. However, the invention should not be limited to any particular theory.

10       An ultrasonic bone healing device 1, in accordance with one form of the present invention, is shown in Figs. 1A and 1B. The healing device 1 is adapted to be employed within the mouth of a human for accelerating the healing and bone regeneration process. As shown in  
15       Fig. 1B, the tooth 12 is secured in the body by bone tissue 10, surrounded by soft gum tissue 16. In the illustrative embodiment, a pocket 13 resulting from gum disease is formed between the bone 10 and soft tissue 16, by recession of bone tissue adjacent the tooth 10.  
20       Treatment of the disorder involves implanting a filler material 14, e.g., bone fragments, etc., into the pocket 13 and placing a membrane 15 or cover over the material and under the soft tissue 16.

25       In the embodiment illustrated, the bone healing device 1 comprises piezoelectric transducer 20 secured in a cast 18 and having connecting wires 22 and a

connector 11 that connects the healing device 10 to an external ultrasonic power supply 3. The external ultrasonic power supply 3 draws its power either from a standard household current through connector 5 as shown, or is operated from a battery within the power supply.

When energized, the power supply 3 activates the piezoelectric transducer 20 to produce ultrasonic waves 24, the cast 18 is made of a flexible material that has an interior portion that conforms to the surface of the soft tissue 16 and the teeth 12 surrounding the bone 10 in the affected area. To enhance transmission of the ultrasonic waves 24 through the soft gingival tissue 16 to the bone 10, a thin coating of gel 8 may be applied onto the interior surface of the cast 18.

The intensity of the ultrasonic waves 24 should not cause tissue heating. It has been found that the intensity may be up to approximately 30 mW/cm<sup>2</sup> which is below the tissue heating range. The frequency of the waves can be in a range from about 20,000 Hertz to above 5,000,000 Hertz. Preferably, the frequency is about 1.5 MHz.

The ultrasonic waves 24 are conducted through the various structures including the cast 18, the gingival tissue 16, the membrane 15, the medication and bone fragments 14 in pocket 13, into the bone 10 and into

the teeth 12. The ultrasonic energy generates microcurrents in the bone 10 and the teeth 12 to enhance the healing and regeneration of the bone 10.

5 The application of ultrasonic energy as set forth in the above embodiment and in the various embodiments hereafter discussed, also has an additional advantage, namely the reduction of bacterial contamination and inflammation at the healing site. The ultrasonic energy retards and reduces bacterial growth and the  
10 inflammation associated with contamination and healing. Thus, the invention promotes and accelerates healing of the bone and the soft tissue by facilitating a decontamination of the site as well as by promoting the generation of microcurrents.

15 Figs. 2A and 2B illustrate an embodiment of the invention employing an ultrasonic bone healing device 2 for enhancing the osseointegration process of an implant 30 located in the jawbone 10. The bone healing device 2 comprises a pair of piezoelectric transducers  
20 20, connecting wiring 22 and (as shown in Fig. 1B) common connector 11 that connects to the external ultrasonic power supply 3. The external power supply draws its power either from a standard household current through a connector 5 or is operated from a  
25 battery within the power supply.

The piezoelectric transducers 20 are encapsulated in cast 18 made of a flexible material that conforms to the surface of the soft tissue 16 surrounding the jawbone 10. The cast also has a recess for receiving the free end of implant 30. To enhance transmission of the ultrasonic waves 24 through the soft gingival tissue 16, a thin coating of gel 8 is applied onto the cast 18.

The intensity of the ultrasonic waves 24 is regulated so as not to exceed the tissue heating range, e.g., approximately 30 mW/cm<sup>2</sup>. The frequency of the waves is in the range noted above and is preferably 1.5 MHz.

The ultrasonic waves 24 are conducted through the cast 18 and the gingival tissue 16 into the bone 10 and the implant 30. The ultrasonic energy generates microcurrents in the bone 10 to enhance the healing of the bone 10 and osseointegration of the implant 30.

Figs. 3A and 3B show an embodiment of a bone healing device 4 similar to the arrangement illustrated in Figs. 2A and 2B in which cast 18 has a pocket 17 formed in the interior surface 26 thereof. The pocket 17 is sealed against the soft tissue 14 by lips 19 which define boundaries of the pocket 17. A volume of gel 26 may be located in the pocket 17 to improve the transmission of the ultrasonic waves 24 emitted from

transducer 21 through the soft tissue 16 and into the jawbone 10.

In the arrangement illustrated in Figs. 3A and 3B, the transducer 21 comprises a multilayer device having two outer layers and an intermediate layer. In operation, the multilayer transducer 21 produces more powerful ultrasonic waves 24.

Figs. 4A and 4B show an embodiment of the invention employing an apertured piezoelectric transducer 23. The transducer 23 is directly attached to the free end of the implant 30 by means of a threaded stud 25 to transmit ultrasonic waves 24 or vibrations directly through the implant 30 and into the jawbone 10. The advantage of this embodiment is that the implant 30 is a good conductor of the ultrasonic waves 24. Thus, the implant 30 conducts the waves 24 directly to the interface between the bone 10 and implant 30 where the osseointegration takes place.

Figs. 5A and 5B show an arrangement similar to Figs. 4A and 4B employing a multilayer piezoelectric transducer 27 configuration with increased ultrasonic power output capability.

Figs. 6A and 6B show another embodiment of the invention employing a bone healing device 34 adapted to engage the free end of the implant 30. In the arrangement illustrated, the device 34 comprises a

resilient transducer support 29, an end cap 29 and a transducer 27 therebetween, e.g., in the arrangement illustrated, the transducer 27 is optionally a multilayer device. The end-cap 28 has a recess providing a close fit to free end of the implant 30. The flexible pad 29 cushions the opposing tooth 31 while it holds the bone healing device 34 against the implant 30. The pad 29 also acts to attenuate ultrasonic energy from the side of the transducer 27 opposite to the teeth under treatment. This embodiment makes the daily attachment of the bone healing device 34 to the implant 30 a much easier task so it can be accomplished with ease by the elderly and people with reduced dexterity.

Figs. 7A-7C show yet another embodiment of the invention in which the bone healing device 36 is an elongated structure similar to the arrangement of Figs. 6A and 6B. The device 36 is adapted to engage one or more teeth 12 and includes an optional multilayer transducer 27, an intermediate flexible pad 29, an end-cap 32 molded to fit the crown of the teeth 12. The pad 29 cushions the opposing teeth 31 while it holds the end cap 32 of the bone healing device 36 against the teeth 12. The ultrasonic waves 24 are transmitted from the piezoelectric crystal stack 27 through the end-cap 32 directly to the teeth 12 and to the jawbone

10 without going through the soft tissue 14. To enhance transmission of the ultrasonic waves 24 into the teeth 12, a thin coating of gel 8 may be applied onto the end-cap 32. The advantage of this embodiment  
5 is that the teeth 12 conduct the ultrasonic waves 24 more efficiently than the soft tissue 16. Also, the waves 24 are conducted directly to the jawbone 10 where the healing and bone regeneration must take place. This embodiment also makes the daily attachment of the  
10 bone healing device 36 to the teeth 12 a much easier task so it can be accomplished with ease by the elderly and people with reduced dexterity.

Figs. 8A-8C show a bone healing device 38 for osseointegration application at the stage of the  
15 implantation procedure when the implant is installed into the jawbone but it is still covered with a soft tissue gum flap 44 during the early stages of the osseointegration procedure. In this arrangement, the ultrasonic waves 24 are transmitted via an end-cap 40  
20 of the transducer 27 through the soft tissue gum flap 44 directly into the implant 30. The advantage of this embodiment is that the implant 30 conducts the ultrasonic waves 24 evenly to the jawbone interface where the osseointegration takes place. The end-cap 40  
25 is cast to spatially conform the soft tissue end flap 44 of the gum covering the implant. The transmission



of the waves 24 is enhanced by the application of a thin layer of gel 8. The device 38, like other embodiments, may utilize a flexible pad 29 to direct ultrasonic energy to the tooth or implant to be treated and to cushion the opposing teeth 31 while the bone healing device 38 is being held in place by the teeth 31 during the treatment.

Fig. 9 shows a multilayer piezoelectric transducer 27 having an induction coil 50 with wires 51 connecting the coil 50 to the transducer 27. The coil 50, transducer 27 and wires 51 are encapsulated within an artificial tooth 56 which may be directly attached to the implant 30 by a bolt 25 to thereby transmit ultrasonic wave 24 vibrations to the jawbone 10. The ultrasonic frequency electrical current may be generated by the ultrasonic power supply 3 is connected by wires 54 to an induction coil 52 which inductively couples the ultrasonic frequency electrical current to coil 50 encapsulated within the artificial tooth 56. The coil 52 may be encapsulated in an insulating material 58, as shown. The advantage of this embodiment is that the transducer 27 can be permanently or temporarily installed by the physician and the implant 30 is not disturbed during the osseointegration process. This embodiment provides a permanently sealed design and eliminates the electrical connections that

the patients may find troublesome. The coil 52 can be placed outside the oral cavity on the outside of the face and held in place comfortably by the patient during the daily treatment. Alternatively, the coil 52  
5 may be positioned proximate the implant 30 in the mouth.

While the preceding description contains many specificities, these should not be construed as limitations on the scope of the invention, but rather  
10 as an exemplification of a preferred and additional embodiments thereof. Many other variations are possible. Skilled artisans will readily be able to change dimensions, shapes and construction materials of the various components described in the embodiments and  
15 adopt the invention to all types of sonic energy applications, from subsonic through sonic to the ultrasonic range. Accordingly, the scope of the invention should be determined not by the embodiments illustrated, but by the appended claims and their legal  
20 equivalents.

WHAT IS CLAIMED IS:

1           1. An apparatus operative in an affected area for  
2           accelerating the process of jawbone healing and  
3           regeneration or reattachment of traumatically loosened  
4           teeth to the jawbone in a patient comprising:

5           a piezoelectric transducer constructed of at least  
6           one active element for contracting and expanding  
7           volumetrically when energized in response to a changing  
8           electrical field and generating vibrations of  
9           ultrasonic energy, said transducer being operative to  
10          transmit said vibrations through the soft tissue toward  
11          the jawbone;

12          securing means for receiving the transducer  
13          therein at a selected location and having a surface  
14          portion formed to conform with the oral anatomy to  
15          position said piezoelectric transducer proximate the  
16          affected area and to secure said piezoelectric  
17          transducer in place thereat;

18          coupling means coupled to the said piezoelectric  
19          transducer extending from the securing means to  
20          transmit ultrasonic frequency electrical signals to  
21          said piezoelectric transducer.

1           2. The apparatus of claim 1 further comprising  
2           means for filling a gap formed between the soft  
3           anatomical tissue and the securing means of the

1 piezoelectric transducer to enhance transmission of  
2 ultrasonic energy from said piezoelectric transducer to  
3 said soft anatomical tissue.

1 3. The apparatus of claim 1 wherein the securing  
2 means has a recess in the surface portion adjacent the  
3 transducer.

1 4. The apparatus of claim 3 further comprising  
2 means to hold and retain a volume of soft ultrasonic  
3 energy transmitting media in the recess between the  
4 means securing the piezoelectric transducer and the  
5 soft anatomical tissue to cause the filling of the gap  
6 therebetween, operative to enhance the transmission of  
7 ultrasonic energy to the jawbone.

1 5. An apparatus for accelerating the process of  
2 jawbone healing and regeneration or reattachment of  
3 traumatically loosened teeth to the jawbone in a  
4 patient comprising:

5 a piezoelectric transducer constructed of at least  
6 one active element for contracting and expanding  
7 volumetrically when energized in response to a changing  
8 electrical field and generating vibrations of  
9 ultrasonic energy, said transducer being operative to

10 transmit said vibrations through the teeth toward the  
11 jawbone;

12 means for connecting the piezoelectric transducer  
13 to the teeth formed to conform to the teeth and to  
14 position said piezoelectric transducer in abutment with  
15 the teeth to transmit ultrasonic energy through the  
16 teeth into the jawbone; and

17 coupling means coupled to the piezoelectric  
18 transducer to transmit ultrasonic frequency electrical  
19 signals to said piezoelectric transducer.

1 6. The apparatus of claim 5 further comprising  
2 means to fill a gap formed between the teeth and the  
3 means connecting the piezoelectric transducer to the  
4 teeth to enhance transmission of ultrasonic energy from  
5 said connecting means of said piezoelectric transducer  
6 to said teeth.

1 7. The apparatus of claim 5 further comprising  
2 means for focusing the ultrasonic energy on the teeth  
3 being treated by attenuating the emission of ultrasonic  
4 energy from the side of the piezoelectric transducer  
5 opposite to the teeth under treatment and to provide a  
6 flexible biting surface for the teeth of the jaw  
7 opposite to the jaw being treated to support and secure

8       said piezoelectric transducer in place during the  
9       treatment process.

1               8. An apparatus for accelerating the process of  
2       osseointegration of implants in the jawbone in a  
3       patient comprising:

4               a piezoelectric transducer constructed of at least  
5       one active element for contracting and expanding  
6       volumetrically when energized in response to a changing  
7       electrical field and generating vibrations of  
8       ultrasonic energy, said transducer being operative to  
9       transmit said vibrations through the soft tissue toward  
10      the jawbone and the implant;

11              securing means formed to conform the oral anatomy  
12      to position said piezoelectric transducer in place  
13      about the implant in the jawbone to secure said  
14      piezoelectric transducer in place during the treatment  
15      process; and

16              coupling means coupled to the said piezoelectric  
17      transducer extending from under the securing means to  
18      transmit ultrasonic frequency electrical signals to  
19      said piezoelectric transducer.

1               9. The apparatus of claim 8 further comprising  
2       means for filling a gap formed between the soft  
3       anatomical tissue and the securing means of the

4 piezoelectric transducer to enhance transmission of  
5 ultrasonic energy from said securing means of said  
6 piezoelectric transducer to said soft anatomical  
7 tissue.

1 10. The apparatus of claim 8 further comprising  
2 means to hold and retain a volume of soft ultrasonic  
3 energy transmitting media between the means securing  
4 the piezoelectric transducer and the soft anatomical  
5 tissue to cause the filling of gaps therebetween, said  
6 energy transmitting media operative to enhance the  
7 transmission of the ultrasonic energy to the jawbone  
8 and the implant.

1 11. An apparatus for accelerating the process of  
2 osseointegration of implants in the jawbone in a  
3 patient comprising:

4 a piezoelectric transducer constructed of at least  
5 one active element for contracting and expanding  
6 volumetrically when energized in response to a changing  
7 electrical field and generating vibrations of  
8 ultrasonic energy, said transducer being operative to  
9 transmit said vibrations through the implant toward the  
10 jawbone;

11 means for connecting the said piezoelectric  
12 transducer to the implant formed to conform to the

13        implant and to position said piezoelectric transducer  
14        in place proximate the implant to transmit ultrasonic  
15        energy through the implant into the jawbone;  
16        coupling means coupled to the piezoelectric  
17        transducer to transmit ultrasonic frequency electrical  
18        signals to said piezoelectric transducer.

1            12. The apparatus of claim 11 further comprising  
2        means for filling a gap formed between the implant and  
3        the means connecting the piezoelectric transducer to  
4        the implant to enhance transmission of ultrasonic  
5        energy from said connecting means of said piezoelectric  
6        transducer to said implant.

1            13. The apparatus of claim 11 further comprising  
2        means for focusing the ultrasonic energy on the implant  
3        by attenuating the emission of ultrasonic energy from  
4        the side of the piezoelectric transducer opposite to  
5        the implant and to provide a flexible biting surface  
6        for the teeth of the jaw opposite to the said implant  
7        to support and secure said piezoelectric transducer in  
8        place during the treatment process.

1            14. An apparatus for accelerating the process of  
2        osseointegration of implants in the jawbone in a  
3        patient comprising:



4           a piezoelectric transducer constructed of at least  
5           one active element for contracting and expanding  
6           volumetrically when energized in response to a changing  
7           electrical field and generating vibrations of  
8           ultrasonic energy, said transducer being operative to  
9           transmit said vibrations through the implant toward the  
10          jawbone;

11          means for securing the piezoelectric transducer to  
12          the implant to transmit ultrasonic energy through the  
13          implant into the jawbone; and

14          coupling means coupled to the piezoelectric  
15          transducer to transmit ultrasonic frequency electrical  
16          signals to said piezoelectric transducer.

1           15. The apparatus of claim 14 wherein the means  
2           for securing the piezoelectric transducer to the  
3           implant comprises a threaded bolt.

1           16. An apparatus for accelerating the process of  
2           osseointegration of implants in the jawbone in a  
3           patient comprising:

4           a piezoelectric transducer constructed of at least  
5           one active element for contracting and expanding  
6           volumetrically when energized in response to a changing  
7           electrical field and generating vibrations of  
8           ultrasonic energy, said transducer being operative to

9       transmit said vibrations of ultrasonic energy through  
10       soft tissue covering said implant and said implant  
11       toward the jawbone;

12           means for connecting the said piezoelectric  
13       transducer to the soft tissue formed to spatially  
14       conform to the soft tissue and to position said  
15       piezoelectric transducer in place on the soft tissue to  
16       transmit said vibrations of ultrasonic energy through  
17       the soft tissue and the implant into the jawbone; and

18           coupling means coupled to the piezoelectric  
19       transducer to transmit ultrasonic frequency electrical  
20       signals to said piezoelectric transducer.

1       17. The apparatus of claim 16 further comprising  
2       means to fill up a gap between the soft tissue and the  
3       means connecting the piezoelectric transducer to the  
4       soft tissue to enhance transmission of ultrasonic  
5       energy from said connecting means of said piezoelectric  
6       transducer to said soft tissue.

1       18. The apparatus of claim 16 further comprising  
2       means for attenuating the emission of ultrasonic energy  
3       from a side of the piezoelectric transducer opposite to  
4       the implant and to provide a flexible biting surface  
5       for the teeth of the jaw opposite to the implant to

6 support and secure said piezoelectric transducer in  
7 place during the treatment process.

1 19. An apparatus for accelerating the process of  
2 osseointegration of implants in the jawbone in a  
3 patient comprising:

4 a piezoelectric transducer constructed of at least  
5 one active element for contracting and expanding  
6 volumetrically when energized in response to a changing  
7 electrical field and generating vibrations of  
8 ultrasonic energy, said transducer being operative to  
9 transmit said vibrations through the implant toward the  
10 jawbone;

11 means to connect the piezoelectric transducer to  
12 the implant to transmit ultrasonic energy through the  
13 implant into the jawbone;

14 inductive coupling means coupled to the said  
15 piezoelectric transducer to transmit ultrasonic  
16 frequency electrical signals from an ultrasonic power  
17 supply located outside of the body to said  
18 piezoelectric transducer.

1 20. A method for accelerating the process of  
2 healing tissue and bone and osseointegration of  
3 implants in a patient comprising the steps of:

4           generating vibrations of ultrasonic energy by  
5       means of a piezoelectric transducer;  
6           transmitting said vibrations through at least one  
7       of the tissue, bone and implant toward the jawbone;  
8           connecting the piezoelectric transducer to at  
9       least one of the tissue, bone and implant;  
10          connecting the transducer to transmit ultrasonic  
11       frequency electrical signals from an ultrasonic power  
12       supply located outside of the body to said  
13       piezoelectric transducer.

1           21. The method of claim 20 further comprising the  
2       step of retarding bacterial contamination and  
3       inflammation for accelerating the healing of said  
4       tissue and bone and osseointegration of implants.

1           22. The method of claim 20 further comprising the  
2       step of selectively directing the ultrasonic energy  
3       towards at least one of the tissue and bone to be  
4       healed and the implant to be osseointegrated.

FIG.1A

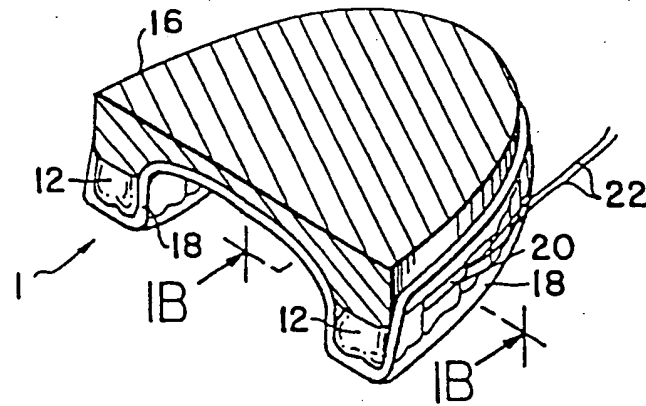


FIG.1B

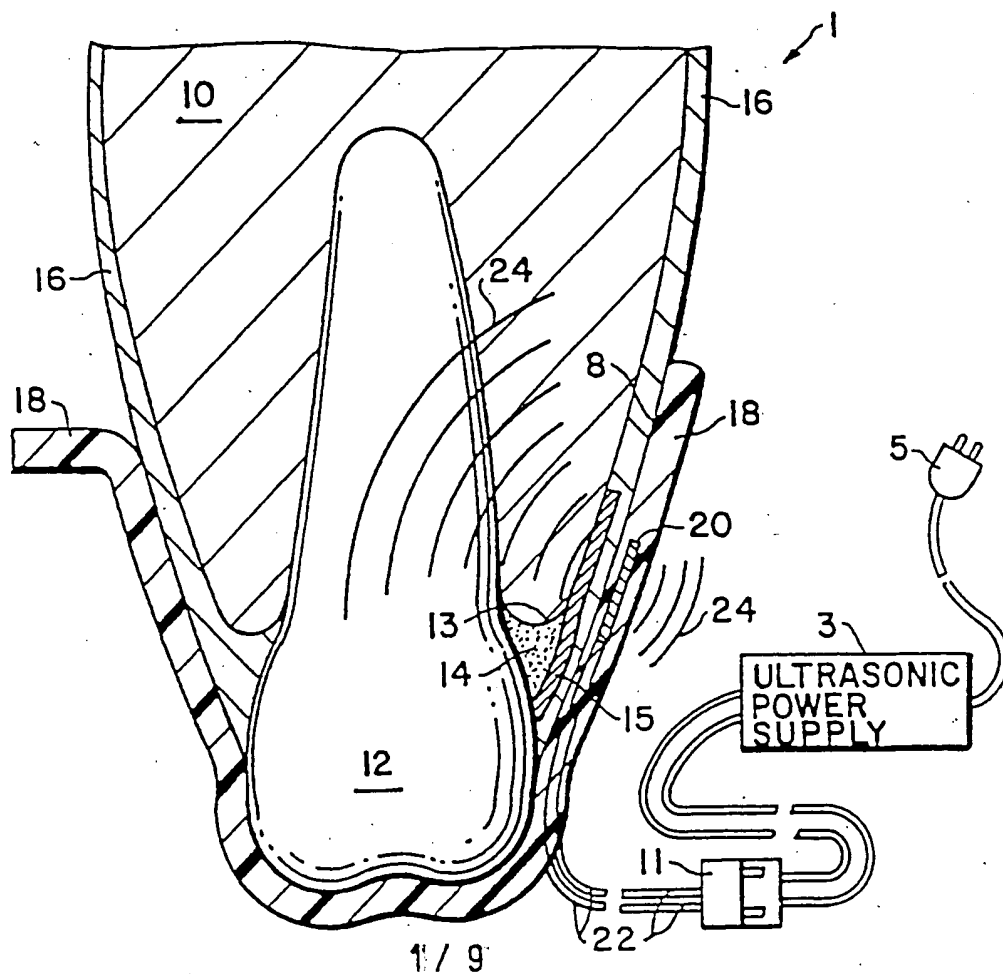


FIG. 2A

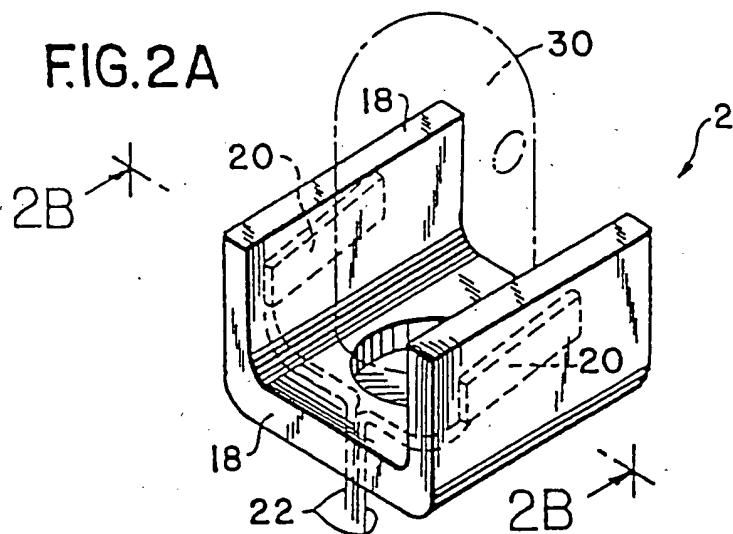


FIG. 2B

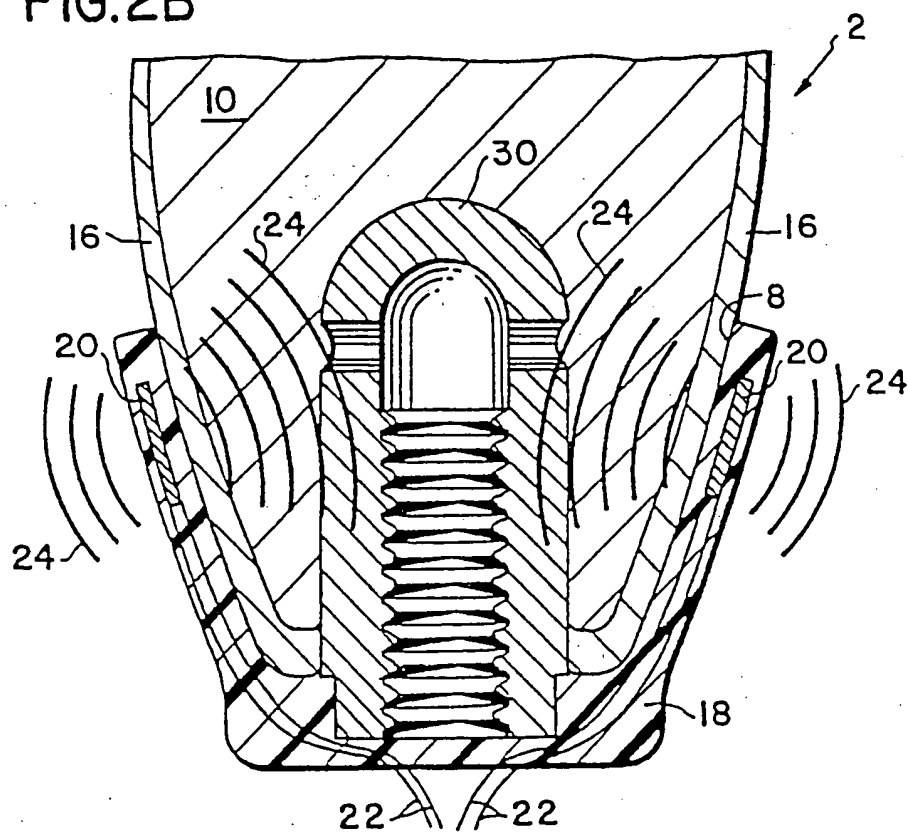


FIG.3A

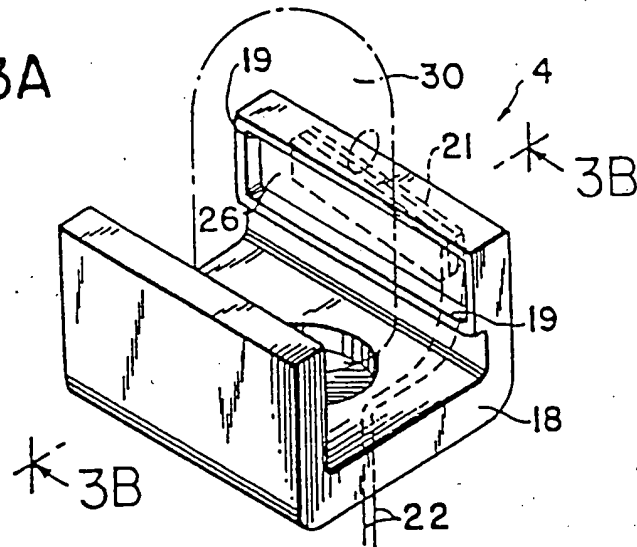


FIG.3B

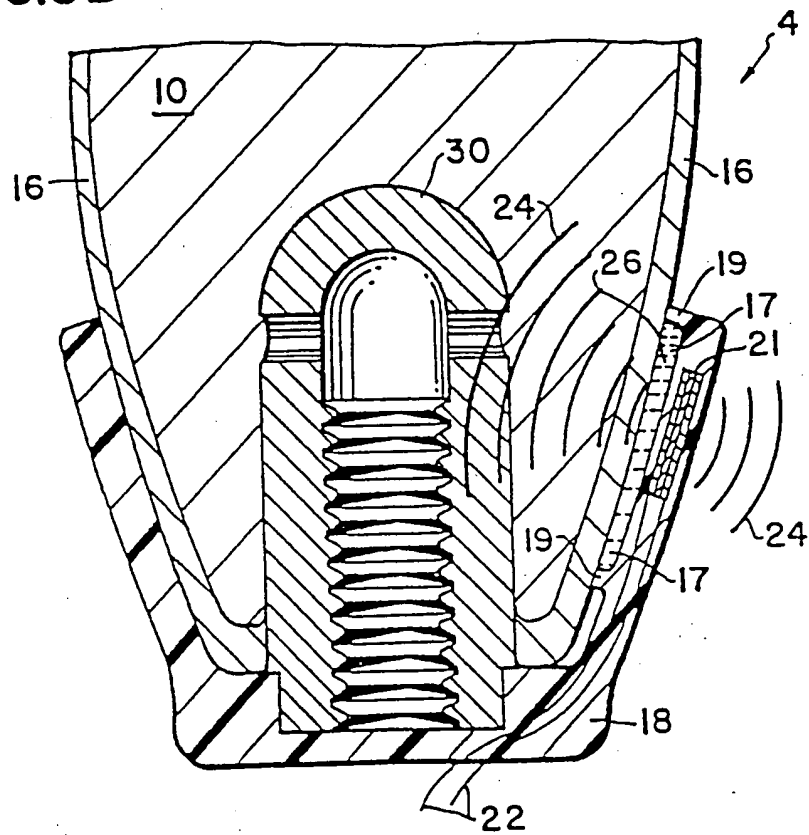


FIG.4A

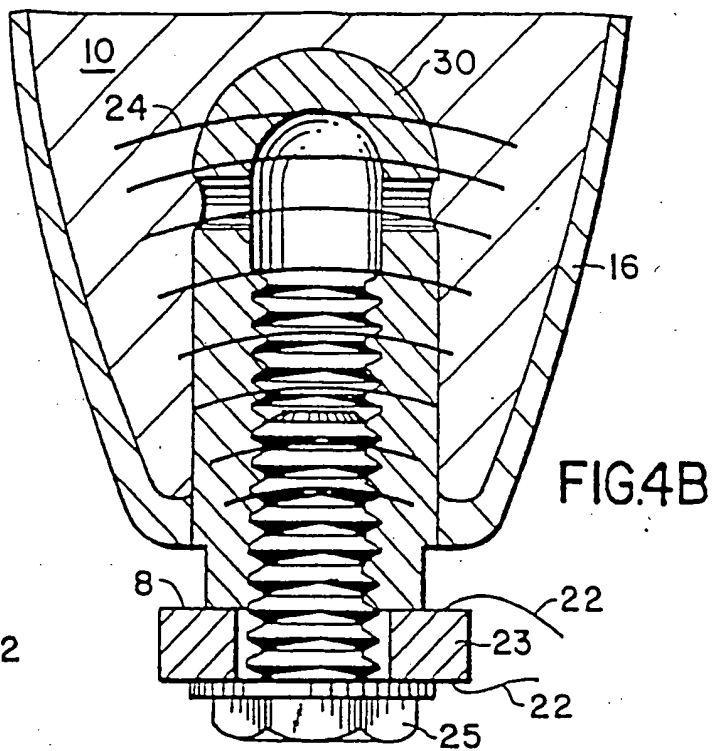
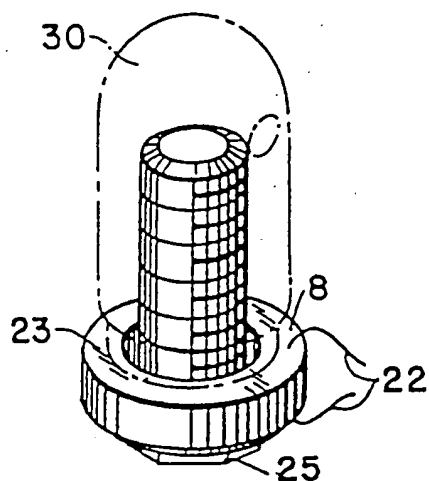


FIG.5A

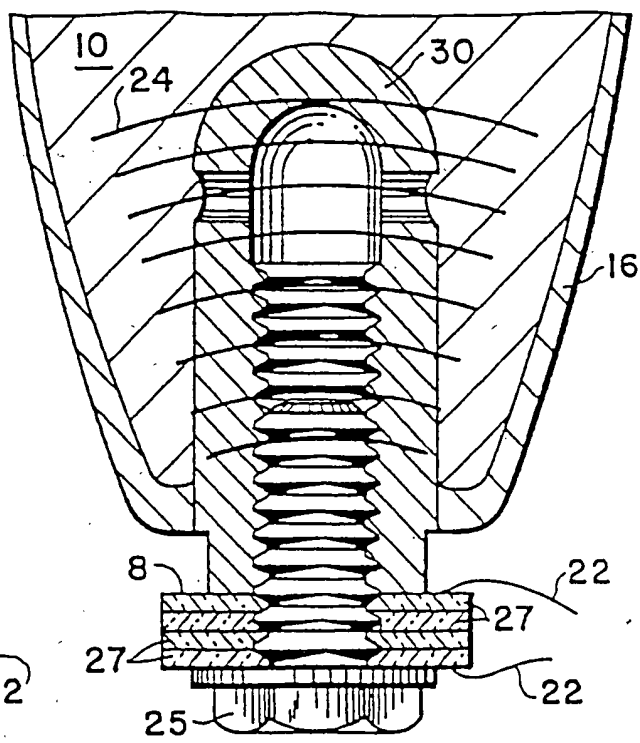
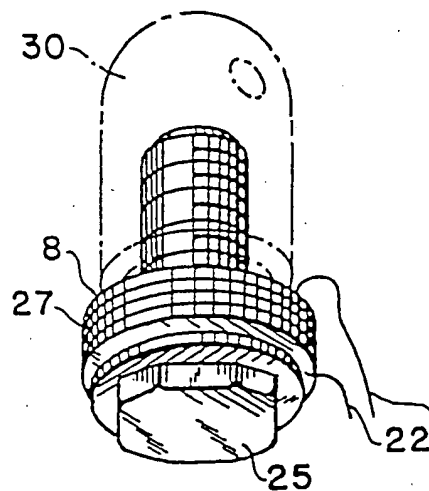


FIG.5B



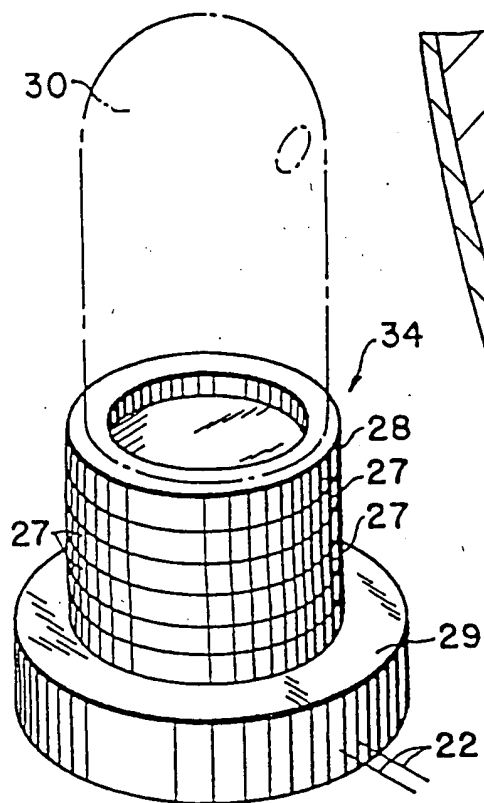


FIG. 6A

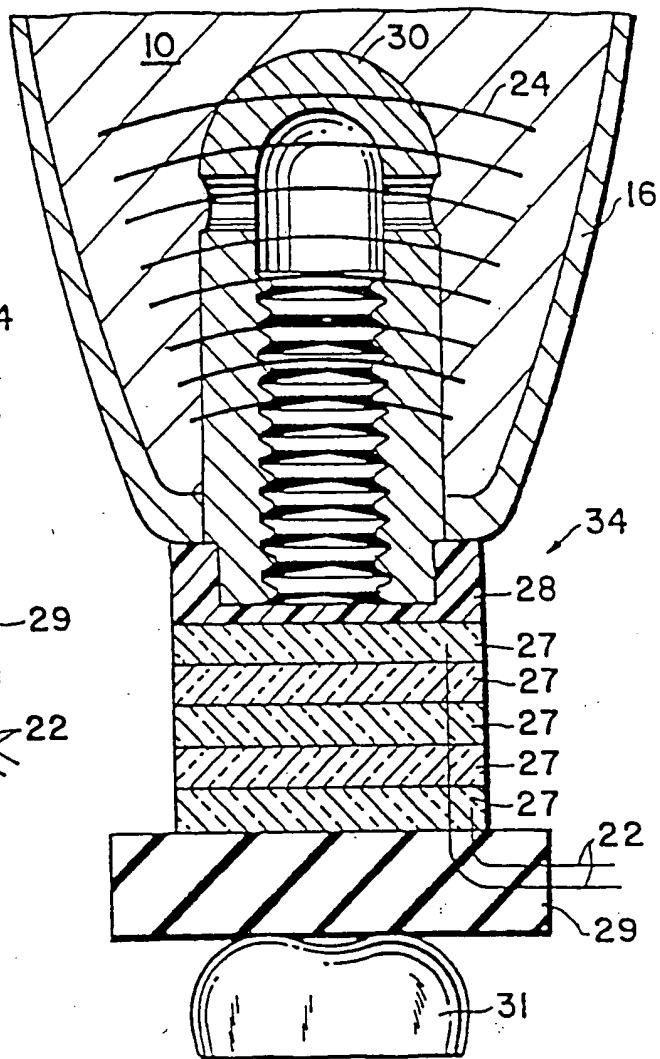


FIG. 6B

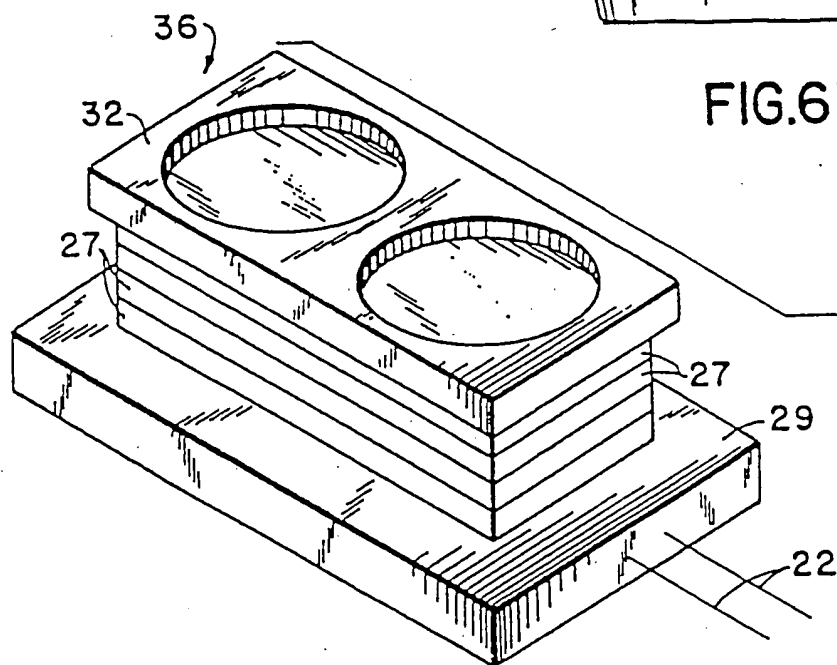
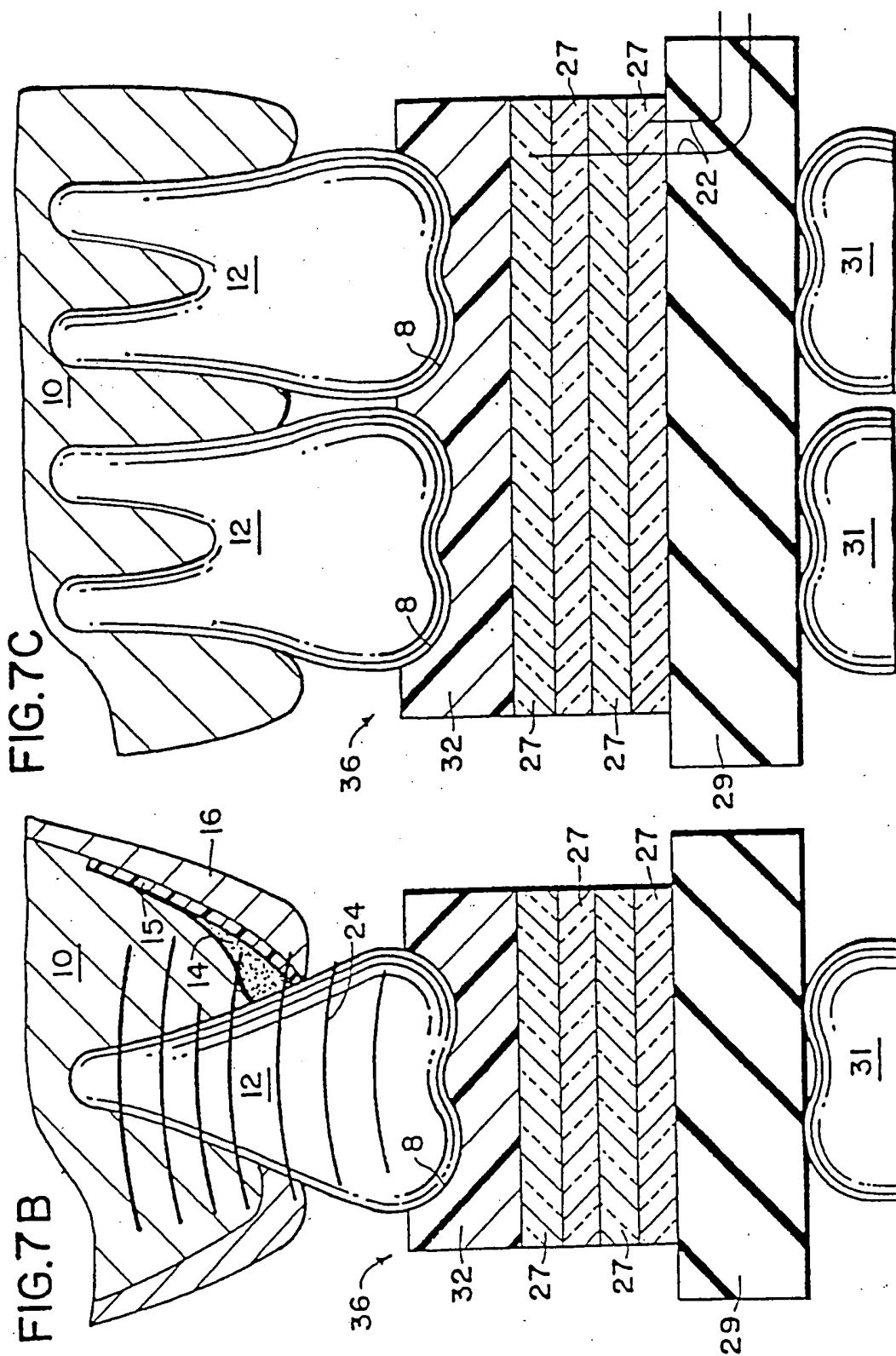


FIG. 7A



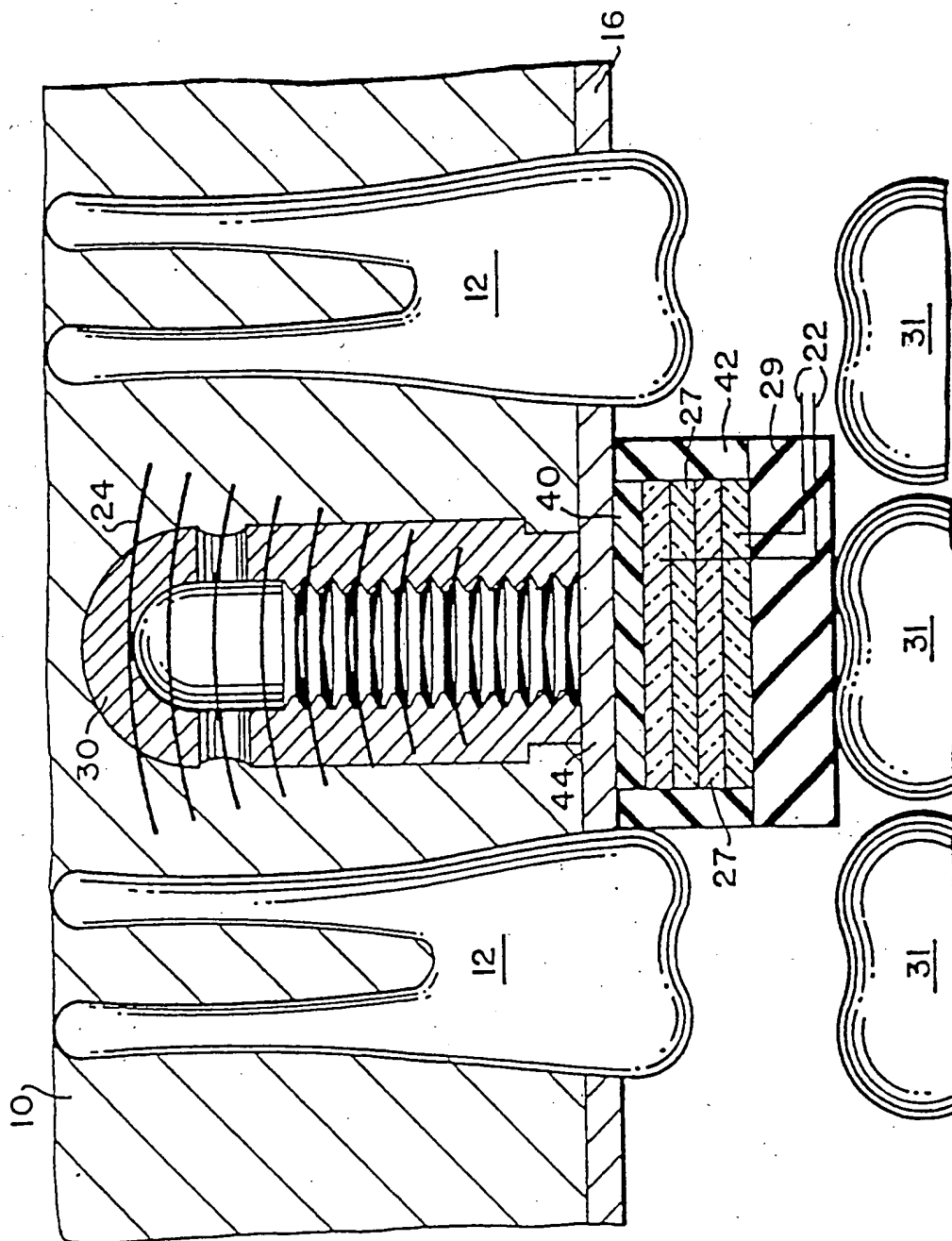


FIG.8B

FIG.8A

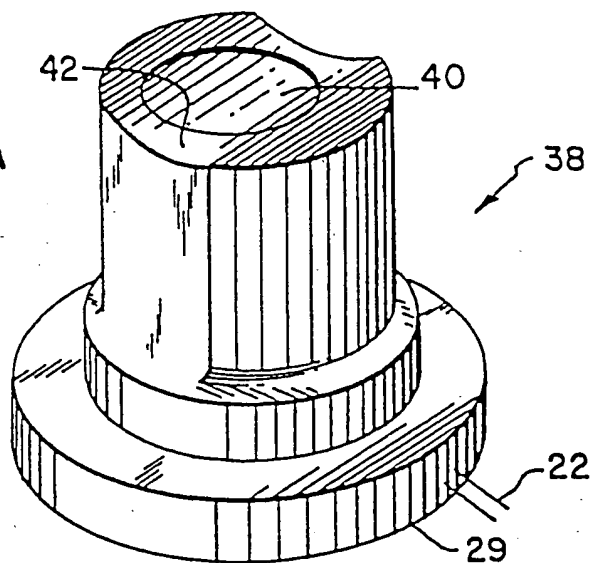
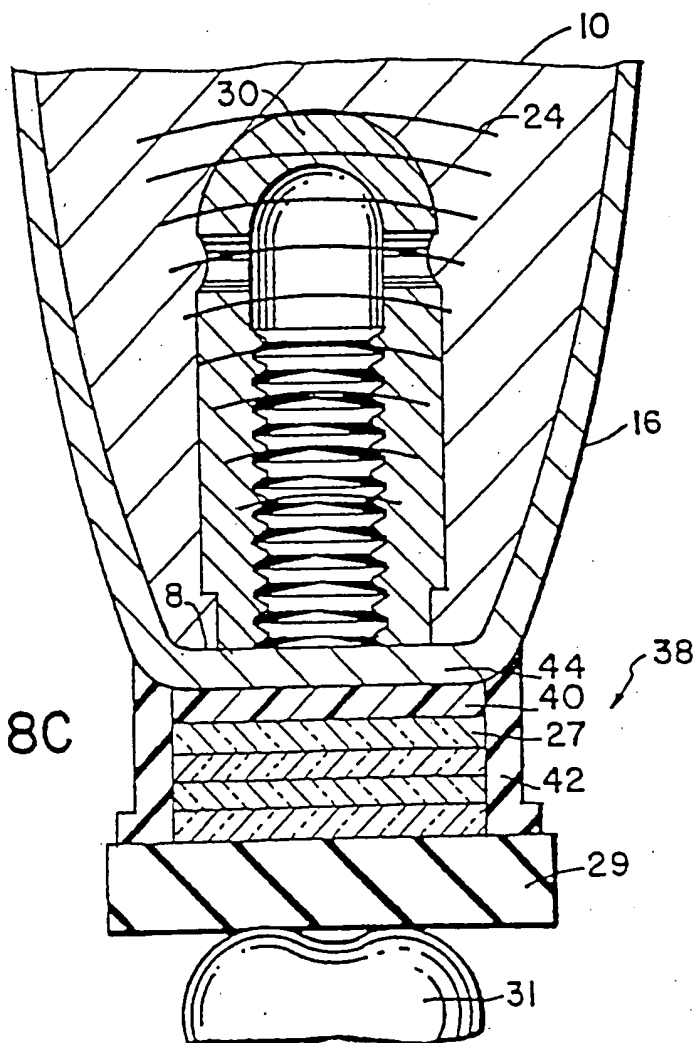


FIG.8C



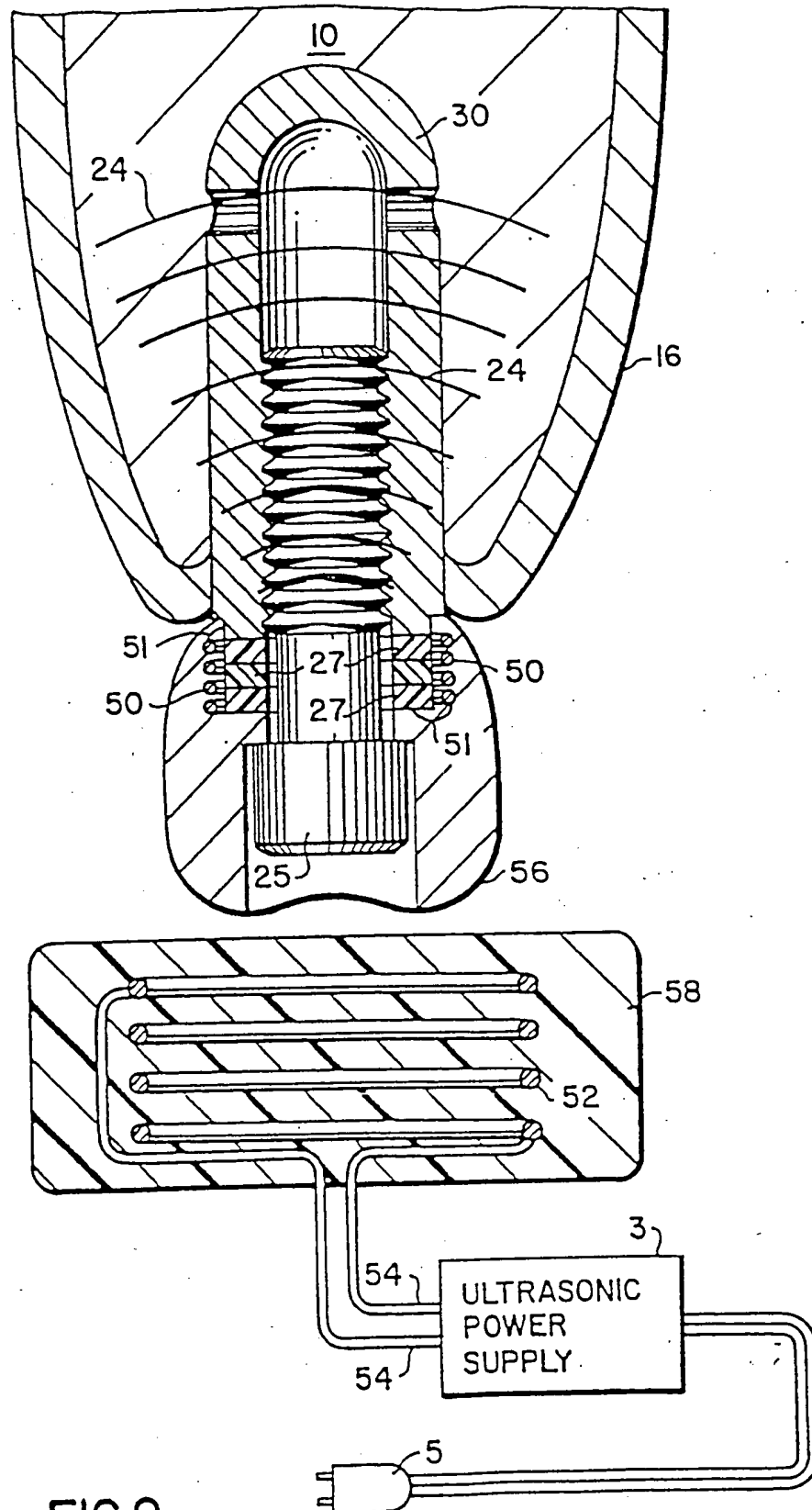


FIG. 9

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/11233

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : Please See Extra Sheet.

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Extra Sheet.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 3,380,446 (MARTIN) 30 April 1968, See entire document.	1-14, 16-19
X	US, A, 4,127,125 (TAKEMOTO ET AL) 28 November 1978, See entire document.	1-14, 16-19
X	US, A, 5,161,521 (KASAHARA ET AL) 10 November 1992, See entire document.	1, 5, 8, 11, 14, 16, 19, 20-22
Y	US, A, 4,530,360 (DUARTE) 23 July 1985, See entire document.	1, 5, 8, 11, 14, 16, 19, 20-22
Y	US, A, 4,244,373 (NACHMAN) 13 January 1981, See entire document.	1, 5, 8, 11, 14, 16, 19, 20-22

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	Y	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means		
*P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

08 JANUARY 1995

Date of mailing of the international search report

10 MAR 1995

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

Krista Pfaffle

Telephone No. (703) 308-2269

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US94/11233

A. CLASSIFICATION OF SUBJECT MATTER:  
IPC (6):

A61B17/56; A61C 19/06

A. CLASSIFICATION OF SUBJECT MATTER:  
US CL :

601/2; 607/51; 433/86

B. FIELDS SEARCHED

Minimum documentation searched  
Classification System: U.S.

601/2; 607/50, 51; 433/86, 215; 623/16; 128/653.1, 660.01

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER: \_\_\_\_\_**

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**